

BUTTAFUOCO, ARCE & PRICE, L.L.C.

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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

<p>Colleen Mary Grobelny and Robert Grobelny her husband</p> <p style="text-align: center;">Plaintiff(s)</p> <p>vs.</p> <p>Baxter Health Care Corporation, The American Red Cross, John Does 1-5, ABC Corporations 1-5 (said names being fictitious)</p> <p style="text-align: center;">Defendant(s)</p>	<p>DOCUMENT ELECTRONICALLY FILED Civil Action No.:2:05-cv-4645-PGS-RJH</p> <p style="text-align: center;">DECLARATION OF GARY M. PRICE, ESQ.</p>
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I , Gary M. Price, of full age , do hereby declare under penalty of perjury as follows:

1. I am an attorney at law of the State of New Jersey and this United States District Court . I am a partner of the law firm of Buttafuoco, Arce & Price, LLC , attorneys for the Plaintiff , in the above captioned matter. Unless otherwise stated I have personal knowledge of the following facts and, if called and sworn as a witness , could an would competently testify thereto.

2. This Declaration is offered in opposition to defendant , Baxter Health Corporation (BHC) and American Red Cross (ARC) motion for Summary Judgment.

3. Attached hereto and made part hereof as Exhibit A , are true and correct copies of the following documents:

Exhibit 1 - Report of John Wurpul, M.S, Ph.D dated June 15, 2006.

Exhibit 2- Declaration of Colleen Grobelny.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on this 31st day of May, 2007.

S/ Gary M. Price,
Gary M. Price, Esq.
garypr@baplawyers.com

EXHIBIT 1

Report of John Wurpel, M.S , Ph.D.

JOHN N.D. WURPEL, M.S., Ph.D.
Pharmacology/Toxicology Information Services

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Date: 15 June 2006

To: Buttafuoco, Arce & Price, L.L.C.
Park Professional Plaza
2509 Park Avenue, Suite 1 C
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Attn: Gary M. Price, Esq.

Draft Report – for Discussion Only !

Re: Colleen M Grobelny

Dear Mr. Price

Ms. Grobelny received intravenous immunoglobulin (IVIG) - Polygam treatment in early (7TH and 8TH) February 2002 to treat idiopathic thrombocytopenia purpura (ITP). Following treatment she was diagnosed with thromboembolic events (requiring the placement of a vena cava filter) and pulmonary embolism; she experienced clotting with thromboemboli occurring in lungs (pulmonary emboli), spleen and left kidney. Ms. Grobelny experienced a reduction in left renal function as a result of the thromboemboli. In preparing my report I reviewed medical records of Ms. Grobelny provided to me.

Infusion of intravenous immune globulin (IVIG) has been identified as a possible risk factor for thrombotic events. Approximately 22% of patients receiving rapid infusion IVIG experience a major thrombotic event (chest pain, myocardial infarction, congestive cardiac failure, severe headache requiring hospitalization, pulmonary embolism, and transfusion related acute lung injury). Infusion concentration should be no more than 5% and infusion rates should be no faster than 0.5 milliliter/kilogram/hour (mL/kg/hour) increased slowly to a maximum rate of 4 mL/kg/hour if well tolerated in patients with thrombotic risk factors such as coronary artery disease, hypertension, cerebrovascular disease and diabetes mellitus.

Thromboembolic events lead to blocked or reduced blood flow with metabolically demanding organs systems being at greatest risk of adverse effects from IVIG. Predictably, the brain (increased incidence of stroke), the heart (increased risk of angina or myocardial infarction), the lungs (pulmonary emboli) and the kidney

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(glomerular damage; prerenal renal failure or tubular damage or acute tubular necrosis – intrinsic renal failure) are most susceptible. Ms. Grobelny experienced pulmonary emboli and renal failure due to the administration of Polygam SD (immune globulin).

Nephrotoxicity due to Immune Globulin or Thromboembolism

Renal dysfunction and/or acute renal failure (ARF) have been associated with the administration of immune globulin intravenous (human) (IGIV) products. The majority of cases of ARF have been successfully managed; however, deaths have been reported.

Hyperosmolality may contribute to renal dysfunction. Histopathologic examination of some of the IGIV associated ARF cases suggests osmotic injury to the proximal renal tubules (acute tubular necrosis, vacuolar degeneration, and osmotic nephrosis). Therapy requiring higher and consecutive doses of IGIV may also be a factor that contributes to renal dysfunction. It is unknown whether age and glomerular filtration rate are among the factors that contribute to renal dysfunction.

Patients that may be at an increased risk for developing ARF include those with any degree of pre-existing renal dysfunction, diabetes, volume depletion, sepsis, paraproteinemia, age greater than 65, and those receiving concomitant nephrotoxic drugs

The most common indications for IVIG were idiopathic thrombocytopenic purpura (37%), nephritis (23%), neuropathy (15%) and anemia (10%). The onset of nephrotoxicity (i.e. renal failure) was 1 to 10 days at doses of 0.4 to 2 grams/kilogram/day. Recovery of renal function occurred within 2 to 60 days of IVIG discontinuation, but the development of end stage renal failure and deaths have occurred. High concentrations of osmotic substances in the IVIG preparation (ie, maltose, sucrose or mannitol) may have contributed to renal tubular injury.

After treatment with intravenous immune globulin (IVIG), swelling and vacuolization of the proximal tubule epithelial cytoplasm have been noted. Serum creatinine and BUN elevations also resulted from IG-induced nephrotoxicity.

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Thromboembolus as a cause of Pulmonary Embolus

Thromboembolism is the most common cause of a pulmonary embolus (PE). The pathophysiologic effects of pulmonary embolism (PE) on pulmonary function result from the direct effects of vascular occlusion and from released vasoactive and bronchoactive mediators. Thus, dyspnea (difficulty breathing), reduced blood oxygen saturation, altered blood pressure and cardiac output result from pulmonary embolism. These alterations in function are further modified by the effect of embolization on cardiac function, primarily through modification of the peripheral venous oxygen saturation (PVO₂).

Small muscle constriction in bronchi and pulmonary arteries occurs rapidly with a decrease in lung compliance, airway resistance increases significantly with a further drop in compliance. Although bronchoconstriction is limited to small airways at first, pneumoconstriction causes volume loss and narrowing of more proximal airways with an increase in total airway resistance. The lung segment which is obstructed by the embolus continues to be ventilated; but since perfusion is blocked, segmental (localized) hypoxia (reduced CO₂ levels) develops, leading to further bronchoconstriction. Atelectasis may occur secondary to surfactant loss, and reflex bronchoconstriction causes wheezing and shortness of breath. Pulmonary hemorrhage following a PE has been found in 33% of patients, while a progression to pulmonary infarction usually occurs in fewer than 10% of patients.

Clinical Data documenting thromboemboli and impaired function following Polygam

1. Renal flow & renogram 2/14/02 – due to left flank pain. Right kidney not obstructed, left kidney demonstrates changes consistent with impaired flow.
2. CT abdomen / pelvis 2/16/02 – “Evidence of thrombosis of all three branches of the left renal venous system ...”. “No evidence of right renal vein thrombosis”.

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3. CT abdomen / pelvis 2/17/02 – confirms left renal thrombosis. "Left pleural effusion and left basilar atelectasis".
4. Ventilation-Perfusion Lung Scan 2/21/02 – "Triple Match" ... Pulmonary embolism of left lower lobe."
5. Renal Flow and renogram 2/27/02 – "Findings consistent with a nonfunctioning left kidney". *D*
6. MRI abdomen w/contrast 3/4/02 - "Thrombosis of the proximal splenic vein with associated splenic infarction".
7. MAG 3 renoflow/renogram 5/7/02 – "Marked impairment of flow and function of the left kidney. Mild to moderate impairment on the right".

The mainstay of therapy for most patients with established venous thromboembolism is anticoagulation therapy with unfractionated or low molecular weight heparin (LMWH) to hasten clinical stabilization and prevent recurrence. Either intravenous unfractionated heparin or LMWH may be used to treat pulmonary embolism (PE).

Heparin is usually given for 5 to 10 days in combination with warfarin, which is started concurrently or shortly after initiating heparin therapy; heparin is continued until the INR is therapeutic.

Thrombolytic agents usually are reserved for hemodynamically unstable patients with a massive PE in whom the benefits of treatment outweigh the risks of serious bleeding complications. Mechanical and surgical means of thrombus extraction may be required for patients in whom thrombolytic therapy fails or is contraindicated.

Ms. Grobelny experienced multiple thromboemboli after receiving Polygam. These documented thromboemboli (pulmonary, splenic and renal) were associated with pathologic events in lung and kidney and permanent reduction in (left) kidney function.

OPINION(S)

Ms. Grobelny experienced thromboembolic events temporally related to the administration of Polygam.

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Thromboemboli were documented in the lung, spleen and kidney (left).

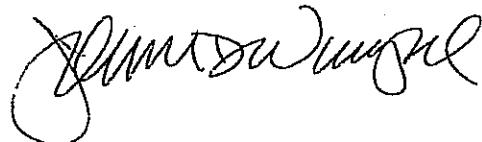
Ms. Grobelny required treatment for these drug-induced (Polygam) adverse effects.

Ms. Grobelny experiences a permanent reduction in renal function due to her Polygam-induced toxicity.

Thank you for referring this interesting case for my consideration. If you have any questions or need further assistance please do not hesitate to contact me.

In appreciation of your time and consideration, I remain

Sincerely



John N.D. Wurpel, M.S., Ph.D.
Associate Professor of Pharmaceutical Sciences

JNDW/twp

EXHIBIT 2

Affidavit of Colleen Grobelny

BUTTAFUOCO, ARCE & PRICE, L.L.C.

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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

Colleen Mary Grobelny and Robert Grobelny her husband Plaintiff(s) vs. Baxter Health Care Corporation, The American Red Cross, John Does 1-5, ABC Corporations 1-5 (said names being fictitious)	DOCUMENT ELECTRONICALLY FILED Civil Action No.:2:05-cv-4645-PGS-RJH AFFIDAVIT OF COLLEEN MARY GROBELNY
Defendant(s)	

State of New Jersey

County of Middlesex

PERSONALLY APPEARED BEFORE ME, the undersigned authority in the aforesaid County and State, the within named, Colleen Mary Grobelny, who first being sworn states as follows:

1. My name is Colleen Mary Grobelny, I am over the age of 18 and of sound mind. I am the plaintiff in this matter. I make this declaration in opposition to Defendant's motion for Summary Judgment.

2. Prior to the thrombotic episodes that I incurred as a result of the administration of the IVIG in this case. I have never been diagnosed with any cardiovascular disease or thrombotic episodes.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Further, Affiant saith not.

Colleen Mary Grobelny
Colleen Mary Grobelny

State of New Jersey

County of Middlesex

BEFORE ME, the undersigned authority, personally appeared Colleen Mary Grobelny who after being duly sworn, states under oath that she signed the foregoing Declaration, and the statements contained herein are true and correct.

SUBSCRIBED AND SWORN TO before me this 31 day of
May, 2007.

Charlotte Macaro
Notary Public

My Commission Expires:

2/2/08

CHARLOTTE M. MACARO
NOTARY PUBLIC OF NEW JERSEY
Commission Expires 2/2/2008

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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

Colleen Mary Grobelny and Robert Grobelny her husband Plaintiff(s)	DOCUMENT ELECTRONICALLY FILED Civil Action No.:2:05-cv-4645-PGS-RJH
vs. Baxter Health Care Corporation, The American Red Cross, John Does 1-5, ABC Corporations 1-5 (said names being fictitious) Defendant(s)	

**BRIEF IN OPPOSITION OF DEFENDANT, BAXTER HEALTH CORPORATION
(BHC) AND AMERICAN RED CROSS (ARC) MOTION FOR SUMMARY JUDGMENT.**

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297 F.3d 242, 247 (3d Cir. 2002).	

STATEMENT OF UNDISPUTED FACTS

Plaintiff objects to the fact set forth in paragraph 5 ,6 and 7 as it specifically relates to the factual determination of that the warnings were approved by the FDA or printed. No where in the documents provided has the Defendant other then the Affidavit of Richard I. Schiff, M.D , Ph.D who did not begin to work for BHC until 2003 , is there any reference or factual support to the statement that the warnings were approved by the FDA. There is in fact, no documents attached to that would indicate the FDA approvals. Therefore we object to references to the FDA approvals.

Plaintiff further objects to paragraph 15 of the Defendant s' Statement of Undisputed Facts in that no documents from the FDA have been produced nor attached and they have not been produced in Discovery.

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INTRODUCTION

Defendant has not established that the product inserts for the product in question were FDA approved.

Plaintiff in this matter claims that the Defendants were negligent in failing to include an adequate warning or instruction with the IVIG. According to the Defendants, they indicate that the FDA approved the inserts, but no evidence has been submitted from the FDA documenting this contention . What they have submitted is the Affidavit of a Representative of BHC. In fact, the Affidavit of Defendants representative Donald , indicates that several approvals occurred regarding this product. He indicates that in 1986 the FDA approved BHC processing of plasma and Gammagard and approved its distribution of Gammagard. No documents from the FDA have been submitted in support of that approval. Mr. Baker further indicates that subsequently, the FDA authorized BHC to process ARC-Collected Plasma for the ARC product known as Polygam. No documentation from the FDA is submitted in support of that statement . Mr. Baker then states that in 1994 the FDA approved the inclusion of a solvent-detergent processing step by BHC , and BHC received FDA approval to distribute Gammagard S/D and Polygam S/D. Again there is no documentation from the FDA supporting this statement. Mr. Baker then states that the package inserts use for Gammagard S/D and Polygam S/D was approved by the FDA in accordance with the code of Federal Regulations. He then attaches an example of the package insert . There is no documentation further to indicate that he FDA approved this package insert.

As such , if the primary focus of the Defendants argument is that FDA approvals were received, there is no documentation from the FDA to support that and the mere statement by a

Representative of the Defendant would be insufficient to establish that fact. As such, the defendant's motion must fail.

The defense arguments that under the New Jersey Product Liability Statute , Plaintiff can not establish failure to warn must be denied due to lack of proofs.

New Jersey Product Liability Law indicates that when a package insert has been approved by the FDA a rebuttable assumption arises , that the warning or instruction is adequate. Implicit in that statement in N.J.S.A 2A:58C-4 is that proof of the approval would be submitted. In this case no such proof has been provided.

Moreover, the New Jersey Product Liability Statute creates a rebuttable presumption that the warning or instructions was adequate.

In this case , assuming that there is some documentation to establish that the FDA did approve the inserts, the only precaution that was given regarding thrombotic events was as follows:

Precautions

General

There is clinical evidence of a possible association between Immune Globulin Intravenous (Human) (IVIG) administration and thrombotic events. The exact cause of this is unknown; therefore, caution should be exercised in the prescribing and infusion of IGIV in patients with a history of cardiovascular disease and thrombotic episodes.

In this case , the plaintiff did no fall in either category of having a history of cardiovascular disease or thrombotic episodes. No warnings were given to Mrs. Grobelny or her doctor regarding thrombotic episodes in patients who did not have a history of cardiovascular disease or thrombotic episodes. As such a genuine question arises as to whether or not a jury would find that the warning indicating that doctor with patients with histories of cardiovascular

disease or thrombotic episodes should use caution in prescribing the infusion of the IVIG. (See attached Affidavit of Colleen Grobelny).

Defendants own arguments and warnings fail to adequately establish plaintiff's theory that the warnings were inadequate. The plaintiff, Mrs. Grobelny was not did fall into either category that the alleged warning made reference to.

Plaintiff acknowledges that her expert John Warpel indicates that the insert makes reference to a thrombotic event however that warning is adequate with persons falling into those categories. The fact that Mrs. Grobelny does not fall into neither category of cardiovascular disease or thrombotic episodes raises and genuine issue of material fact on the product liability claim, and therefore Defendant has not sustained its burden of proof with respect to this motion for summary judgment and therefore is not entitled to summary judgment.

STANDARD OF REVIEW : SUMMARY JUDGMENT

Rule 56 in the Federal Rules of Civil Procedure provides that Summary Judgment must be granted only when the evidence contained in the record , including , "the pleadings , depositions, answers to interrogatories , and admissions on file together with the Affidavits , if any show that there is no genuine issue was to any material fact and that the moving party is entitled to judgment as a matter of law" Fed. R. Civ. P. 56 (c) ; *Anderson v. Consolidated Rail Corp.*, 297 F.3d 242, 247 (3d Cir. 2002).

LAW AND ARGUMENT

Defendant, has not meet there burden of proof and therefore are not entitled to Summary Judgment .

There is no substantial proof nor any documents submitted into evidence to verify Defendants statement that the FDA approved the package insert provided with the IVIG. That alone requires that this motion be dismissed.

Further Defendants argument that they provided the warning to a Learned Intermediary also fails in view of the fact that the warning that the Defendants, rely upon, only indicated caution should be used for patients with history of cardiovascular disease and prior thrombotic episodes. That is not the case here.

Defendants are not entitled to protection under the New Jersey Product Liability Statute in that they have not established that the package insert or drug was approved by the FDA. Moreover, plaintiff has overcome the rebuttable presumption in that it is clear that she did not fall into either category that warnings were allegedly given concerning. N.J.S.A 2A:58C-4. That statute provides:

In any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning for instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction. And adequate product warning or instruction is one that a reasonable prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to , the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to , the prescribing physicians. If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the Federal Food and Drug Administration under the " Federal Food, Drug, and Cosmetic Act, "52 Stat. 1040 , 21 U.S.C 301 et seq. or the "Public Health Service

Act, “ 58Stat. 682 U.S.C §201 et seq., a rebuttable presumption shall arise that the warning or instruction is adequate. For purposes of this section, the terms “drug”, “device”, “food”, and “food additive” have the meaning defined in the “Federal Food, Drug and Cosmetic Act.”

In order for warning or instruction to be presumed to be adequate, first there must be proof that it was approved by the FDA .

Defendant does not argue that the provided any other warnings other then the package inserts to the plaintiff's physician . Therefore assuming the defendant only warned the plaintiff's physician of that caution should be utilized in patients with a history of cardiovascular disease and thrombotic episodes then it is clear that such warnings were not adequate because the plaintiff did not fall into either category. No other warnings were provided to the plaintiff's treating physicians and as such there is a genuine issue of material fact as to whether or not the warning was sufficient.

2. Defendants failed to prove that that Dr. Fang was a Learned Intermediary to Whom Defendants discharged their obligation to warn .

It is undisputed in this matter that the thrombotic episodes suffered by the plaintiff were caused by the infusion of the IVIG. Ms. Grobelny's expert Dr. John Wurpel states in his deposition that these documented thromboembolic were associated with pathological events in the lung , kidney and permanent reduction in left kidney function, they were associated with the infusion of the Polygam on the 7th and 8th of February 2002.

Initially it should be noted that without any FDA documents indicating approval , then no warning should be deemed to be adequate and therefore an issue of material facts results.

When the general precautions is viewed, most favorably to the plaintiff in this case, it is

inadequate. Defendant is trying to extract a specific sentence from the warning to establish that the warned they intermediary , Dr. Fang, that there is clinical evidence of possible association between Immune Globulin intravenous administration and thrombotic events. However, within the same paragraph , it says the exact cause of this is unknown; it then goes on to tell the doctor that therefore, caution should be exercised in prescribing an infusion of IVIG in patients with history of cardiovascular disease or thrombotic episodes. A simple reading or that precaution would indicate that the only patients that a doctor needs to concern themselves with from possible thrombotic events are patients with a history of cardiovascular disease or thrombotic episodes. Since Mrs. Gobelny did not fall in any category then they did not advise Dr. Fang of any other side effects.

Thus defendant's argument that Dr. Fang was a Learned Intermediary is flawed. The "Learned Intermediary" in this case was only told to concern himself with patients with that had cardiovascular disease or thrombotic episodes. Conversely, what the defendants were telling the doctor is that otherwise, this is a safe product and you should not be concerned with infusing patients that did not have cardiovascular disease or thrombotic events.

As such we submit to the court that there is a genuine issue of material fact regarding the adequacy of the warnings. Defendant did not provided, plaintiffs doctor with significant information and therefore are not entitled to any protection under the Learned Intermediary doctrine , in fact the defendant may have mislead Dr. Fang of any particular risk other then infusing the IVIG into patients that had cardiovascular disease or thrombotic episodes.

Defendants did not discharge their duty to provide adequate warnings by the package insert.

CONCLUSIONS

Defendants have failed to establish that they are entitled to Summary Judgment , there is no evidence or fact that the FDA has in fact approved the drug or the package insert other then the self serving Affidavits of the Defendant s. Further plaintiff has rebutted that the assumption that the warning was adequate and that the warning was limited only as to patients that has cardiovascular disease or thrombotic events for which plaintiff was not in either category. Defendants are not entitled to any protection under Learned Intermediary doctrine because their warning only raised concern about a certain class of patients for which the plaintiff did not fall in. As such the defendants are not entitled to Summary Judgment. We therefore respectfully request that the motion for Summary Judgment be denied in its entirety.

Respectfully submitted this, 31st day of May , 2007.

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**UNITED STATES DISTRICT COURT
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<p>Colleen Mary Grobelny and Robert Grobelny her husband</p> <p style="text-align: center;">Plaintiff(s)</p> <p>vs.</p> <p>Baxter Health Care Corporation, The American Red Cross, John Does 1-5, ABC Corporations 1-5 (said names being fictitious)</p> <p style="text-align: center;">Defendant(s)</p>	<p>DOCUMENT ELECTRONICALLY FILED</p> <p>Civil Action No.:2:05-cv-4645-PGS-RJH</p> <p>CERTIFICATE OF SERVICE</p>
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I hereby certify that on the date set forth below, a copy of a Brief in Opposition to Defendant BHC and ARC Notice of Motion for Summary Judgment, Statement of Undisputed Facts, Declaration of Gary M. Price, Esq. , Affidavit of Colleen Grobelny and this Certification of Service, all of which were electronically filed today on behalf of plaintiff Colleen Grobelny , were served via electronic service and regular mail to the following:

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Lee Davis Thames, Esq.
P.O Box 22567
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Sterns & Weinroth, P.C.
Attn: Christopher E. Torkelson
50 West State Street, Suite 1400
P.O. Box 1298
Trenton, NJ 08607-1298

I hereby certify that the foregoing statement made by me is true. I am aware that if the foregoing statement made by me is willfully false, I am subject to punishment.

By: S/Theresa A. Kauffmann-Macko
Theresa A. Kauffmann-Macko
Legal Assistant to Gary M. Price, Esq.
Buttafuoco, Arce & Price, LLC

Date: May 31, 2007